REMARKS

Claim Status

Claims 1, 6, 8, 9, 23, 25-27 and 29-38 are pending in the present application.

Claims 2-5, 7, 10-22, 24 and 28 were previously canceled. No additional claims fee is believed to be due.

Claim 36 has been amended to remove recitation of "prevention of Type II Diabetes".

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §112, First Paragraph

The Office Action States that Claim 36 is rejected because the specification does not reasonably provide enablement for preventing type II diabetes in a subject with a HIPE foam. The rejection of claim 36 is now moot in view of the deletion of the term "prevention of Type II Diabetes".

Applicants therefore respectfully request withdrawal of the rejections under 35 U.S.C. § 112, First Paragraph.

Rejection Under 35 USC §102(b) Over Bailly et al. (6,030,953)

Claims 1, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailly et al. (6,030,953). The Examiner states that Bailly et al. teaches a composition comprising chitosan (a HIPE foam) in combination with an inhibitor of gastrointestinal lipase (a lipase inhibitor). Applicants respectfully traverse this rejection based on remarks contained herein.

Under § 102, anticipation requires that all the claim elements appear in a single prior art document. "A Claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 citing *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987). "The Identical invention must be shown in as complete detail as is contained in the ... Claim." MPEP § 2131 citing

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2D 1913, 1920 (Fed. Cir. 1989).

The present invention requires in Claim 1 a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; *wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc*; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof. The current specification teaches that a high internal phase emulsion foam are prepared by polymerization of the oil phase of certain water-in-oil emulsions having a relatively high ratio of water phase to oil phase, commonly known in the art as "HIPE." Therefore, a polymeric foam material which results from the polymerization of such emulsions is referred to herein as a "HIPE foam." HIPE foams comprise a generally lipophilic or amphiphilic, flexible or semi-flexible, nonionic polymeric foam structure of interconnected open-cells. Therefore the current application is not claiming the entire genus of polymeric material but calls out specific polymeric material that is present in the foam that is claimed and described in the current specification that must be nondigestible, non-absorable, open-celled polymeric foam and a high internal phase emulsion foam. Bailly et al. discloses an inhibitor of gastrointestinal lipase and at least one compound selected from the group consisting of chitosan, its derivatives and salts thereof. See Column 1, lines 43-47. Bailly et al. discloses that chitosan is superior over microcrystalline cellulose in reducing anal leakage of oil. *See* Column 3, lines 20-23. Bailly et al. does not teach or suggest a HIPE foam having a density of less than about 0.1 g/cc.

The present invention cannot be anticipated by this reference. Since Bailly et al. does not disclose each and every element of the present application; it cannot as a matter of law anticipate the present invention.

Accordingly, Claims 1, 6, 8 and 9 are novel over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

The Rejection Under 35 U.S.C. § 102(e) Over Daggy et al. (6,607,749)

Claims 1, 6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Daggy et al. (6,607,749). The Examiner states that Daggy et al. teaches a composition comprising methylcellulose (a HIPE foam) in combination with a lipstatin derivative (a lipase inhibitor) and the composition is compressed into a tablet. Applicants respectfully traverse this rejection based on the remarks contained herein.

The present invention requires in Claim 1 a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; *wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc*; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof. The current specification teaches that a high internal phase emulsion foam are prepared by polymerization of the oil phase of certain water-in-oil emulsions having a relatively high ratio of water phase to oil phase, commonly known in the art as "HIPE." Therefore, a polymeric foam material which results from the polymerization of such emulsions is referred to herein as a "HIPE foam." HIPE foams comprise a generally lipophilic or amphiphilic, flexible or semi-flexible, nonionic polymeric foam structure of interconnected open-cells. Therefore the current application is not claiming the entire genus of polymeric material but calls out specific polymeric material that is present in the foam that is claimed and described in the current specification that must be nondigestible, non-absorable, open-celled polymeric foam and a high internal phase emulsion foam. Daggy et al. discloses a swallowable solid dosage form of a combination product which contains a bulking soluble fiber, preferably methylcellulose, which is convenient to take and transport, is preferably sugar free, and

has a lipstatin derivative, preferably orlistat. See Column 2, lines 55-59. Daggy et al. does not teach or suggest a HIPE foam having a density of less than about 0.1 g/cc.

The present invention cannot be anticipated by this reference. Since Daggy et al. does not disclose each and every element of the present application; it cannot as a matter of law anticipate the present invention.

Accordingly, Claims 1, 6, 8 and 9 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Niazi (6,251,421)

Claims 23 and 25-27 have been rejected under 35 USC §103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Niazi (6,251,421). The Examiner states that Bailly et al. and Daggy et al. are applied as before. The Examiner concedes that Bailly et al. and Daggy et al. do not teach the instant composition is used in a kit. The Examiner states that Niazi teaches that compositions can be in the form of commercial packs containing a lipase inhibitor and instructions for its use in the treatment of obesity or hyperlipidemia. Applicants respectfully traverse this rejection based on the remarks contained herein.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some apparent reason, i.e., some teaching, suggestion, or motivation, to modify reference teachings (USPTO Examination Guidelines for Determining Obviousness in View of *KSR Int'l. Co., v. Teleflex, Inc.*, No. 04-1350 (US, Apr. 30, 2007)). Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all the claim limitations (MPEP 2143).

For the reasons that follow, Applicants submit that, even when combined, Bailly et al. and Daggy et al. fail to teach or suggest all of the claim limitations of independent claims 23 and 27. Bailly et al. discloses an inhibitor of gastrointestinal lipase and at least one compound selected from the group consisting of chitosan, its derivatives and salts thereof. See Column 1, lines 43-47. Bailly et al. discloses that chitosan is superior over microcrystalline cellulose in reducing anal leakage of oil. *See* Column 3, lines 20-23. Bailly et al. does not teach or suggest a HIPE foam having a density of less than about 0.1 g/cc.

Daggy et al. discloses a swallowable solid dosage form of a combination product which contains a bulking soluble fiber, preferably methylcellulose, which is convenient to take and transport, is preferably sugar free, and a lipstatin derivative, preferably orlistat. See Column 2, lines 55-59. Daggy et al. does not teach or suggest a HIPE foam having a density of less than about 0.1 g/cc.

The current invention is directed towards compositions comprising a non-digestible, non-absorbable, open-celled polymeric foam wherein the compositions are useful for the purpose of sequestering aqueous and/or hydrophilic materials present in the gastrointestinal tract, thereby ameliorating diarrhea and/or loose stools. *See* Applicants' specification page 6, lines 7-10. In order to provide a high level of efficacy, it is desirable that the foams useful in the present invention have a high capacity to sequester or bind materials present in the gastrointestinal tract. *See* Applicants' specification page 10, lines 28-30. For convenient dosage regimens, it is desirable that the effective dose occupies a relatively small volume on ingestion. *See* Applicants' specification page 10, lines 30-31. It is thus desirable that the foams are highly compressible and sufficiently resilient to allow re-expansion of the foam in the gastrointestinal tract after long periods of storage in a highly compressed state. *See* Applicants' specification page 10-11, lines 31 & 1-2. In order to provide a high capacity and a high degree of compressibility, the foam should have a relatively high void volume. See Applicants' specification page 11, lines 7-8. A high void volume is characteristic of low-density foams. See Applicants' specification page 11, line 8. The current invention claims a kit comprising a first composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said first composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof; and a second composition comprising a lipase. Neither Bailly et al. nor Daggy et al. teach or suggest a kit comprising a first composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a

polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc.

Niazi discloses pharmaceutical compositions containing an effective amount of an inhibitor of gastrointestinal lipase, and an effective amount of at least one compound selected from the group consisting of psyllium fiber or husk, its derivatives and salts thereof. See Column 1, lines 54-59. Niazi does not teach or suggest combining enzyme inhibitors with foam.

Therefore, there is no teaching or suggestion in Bailly et al. or Daggy et al. and Niazi for a kit comprising a first composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc. Because there is no teaching or suggestion at all, in any of the cited documents, of a HIPE foam having a density of less than about 0.1 g/cc, there can be no expectation of success.

Even assuming *arguendo* that one were to combine Bailly et al. or Daggy et al. and Niazi one would still fall short of the Applicants' claimed invention only to arrive at an inhibitor of gastrointestinal lipase with chitosan or methylcellulose and psyllium fiber or husk.

Accordingly, Claims 23 and 25-27 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Shiveley et al. (5,817,704) and further in view of Niazi (6,251,421)

Claims 29-38 have been rejected under 35 USC §103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Shiveley et al. (5,817,704) and further in view of Niazi (6,251,421). The Examiner states that the teachings of Bailly et al., Daggy et al., and Niazi are applied as before and the Examiner concedes that the cited references do not teach the glass transition temperature from about -40 °C to 90 °C to form said oral dosage forms. The Examiner states that Shiveley et al., teaches that foams intended for applications requiring flexibility should contain at least in continuous region having a Tg as low as possible is well-known in the art.

Applicants assert that the arguments presented above regarding Bailly et al., Daggy et al. and Niazi in traversing the § 103(a) rejection also apply to the present rejection. The references do not teach or suggest a composition that comprises, *inter alia*, a HIPE foam having a specific surface area per foam volume of at least about 0.01 m^2/cc.

Shiveley et al. discloses a HIPE-derived heterogeneous polymeric foam structure of interconnected open cells, wherein the foam structure has at least two distinct regions. See Column 3, lines 32-35. Shiveley et al. discloses that the heterogeneous polymeric foams are useful in applications involving energy dissipation (e.g. acoustic and mechanical insulation), thermal insulation, filtration, absorbent cores in absorbent articles (e.g. disposable diapers, incontinence garments, catamenials such as tampons and sanitary napkins, etc.), environmental waste oil sorbents, and as absorbent components in bandages or dressings, to apply paint to various surfaces, in dust mop heads and wet mop heads, in dispensers of fluids, in packaging, in shoes, in odor/moisture sorbents, in cushions, and in gloves. See Column 24-25, lines 66-67 & 1-27. The current invention is directed towards compositions comprising a non-digestible, non-absorbable, open-celled polymeric foam wherein the compositions are useful for the purpose of sequestering aqueous and/or hydrophilic materials present in the gastrointestinal tract, thereby ameliorating diarrhea and/or loose stools. *See* Applicants' specification page 6, lines 7-10. The current invention claims a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a specific surface area per foam volume of at least about 0.01 m^2/cc; and a glass transition temperature (Tg) from about -40°C to about 90°C; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacra lipophilic material ylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof. Shiveley et al. does not teach or suggest a compositions suitable for oral administration to an animal.

Therefore, there is no teaching or suggestion in Bailly et al. or Daggy et al., Shiveley et al., and Niazi for a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a specific surface area per foam volume of at least about 0.01 m^2/cc; and a glass transition temperature (Tg) from about -40°C to about 90°C.

Even assuming *arguendo* that one were to combine Bailly et al. or Daggy et al., Shiveley et al., and Niazi one would still fall short of the Applicants' claimed invention only to arrive at an inhibitor of gastrointestinal lipase with chitosan or methylcellulose, psyllium fiber or husk, and a HIPE-derived heterogeneous polymeric foam structure of interconnected open cells, wherein the foam structure has at least two distinct regions.

Accordingly, Claims 29-38 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

CONCLUSION

This Response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing entry of the amendments presented herein, reconsideration of this application and allowance of the pending claims are respectfully requested.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY

By /Cynthia L. Clay/
Cynthia L. Clay
Registration No. 54,930
(513) 983-9764

Date: August 25, 2010
Customer No. 27752